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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/662,808 | 09/16/2003 | Sylvie Roux | 03495.0174-02000 | 2497 |
| 22852 7590 08/17/2009 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | | |
| EXAMINER CHEN, SHIN LIN | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1632 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 08/17/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/662,808

Applicant(s)

ROUX ET AL.

Examiner

Shin-Lin Chen

Art Unit

1632

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32, 33 and 68-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 80 and 93 is/are allowed.
- 6) ☒ Claim(s) 32 and 33 is/are rejected.
- 7) ☒ Claim(s) 68-79 and 81-92 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Upon further consideration of the claimed invention of the instant application, the finality of the Official action mailed 1-29-09 has been withdrawn. Action of merits follows.

Applicants' amendment filed 6-18-09 has been entered. Claim 80 has been amended. Claim 93 has been added. Claims 32, 33 and 68-93 are pending and under consideration.

Double Patenting

1. Claim 81 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 68. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
2. Claim 82 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 69. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
3. Claim 83 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 70. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

4. Claim 84 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 71.
When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
5. Claim 85 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 72.
When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
6. Claim 86 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 73.
When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
7. Claim 87 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 74.
When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
8. Claim 88 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 75.
When two claims in an application are duplicates or else are so close in content that they both

cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

9. Claim 89 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 76. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

10. Claim 90 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 77. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

11. Claim 91 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 78. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

12. Claim 92 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 79. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim

to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for increasing the concentration of tetanus toxin or a fusion protein comprising a fragment C of the tetanus toxin (TTC) in neuromuscular junction (NMJ) by injecting a tetanus toxin or a fusion protein comprising a fragment C of the tetanus toxin to the neurons and injecting brain derived neurotrophic factor (BDNF), GDNF or neurotrophin (NT) 4 into Levator auris longus (LAL) muscle or gastrocnemius muscle of mice, does not reasonably provide enablement for a method of increasing the transport of tetanus toxin or a fusion protein comprising a fragment C of the tetanus toxin (TTC) in a neuron by administering to the neuron a BDNF, GDNF or neurotrophin (NT) 4 alone without the presence of a tetanus toxin or a fusion protein comprising a fragment C of the tetanus toxin in the neuron. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considered whether the claimed invention provides sufficient guidance to make and use the claimed invention, if not, whether an artisan would have required undue experimentation to make and use the claimed

invention and whether working examples have been provided. When determining whether a specification meets the enablement requirement, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue" (In re Wands, 858 F.2d at 737, 8 USPQ2d 1400, 1404 (Fed. Cir.1988)).

Furthermore, the USPTO does not have laboratory facilities to test if an invention with function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

Claims 32 and 33 are directed to a method of modulating the transport in a neuron of a tetanus toxin or a fusion protein comprising a fragment C of the tetanus toxin comprising administering to the neuron a BDNF, a NT-4 or GDNF to modulate the neuronal transport of said tetanus toxin or fusion protein. Claim 33 specifies the BDNF, GDNF or NT-4 increases the internalization of the tetanus toxin or fusion protein at a neuromuscular junction.

The specification discloses that co-injection of GFP-TTC with either BDNF or NT-4 into Levator auris longus (LAL) muscle or gastrocnemius muscle of mice increases concentration of GFP-TTC at the neuromuscular junction as compared to control (e.g. p. 32-35, example 8-10) and localization of GFP-TTC at the NMJ is rapidly induced by neurotrophic factors such as BDNF, NT-4 and GDNF but not NGF, NT-3 and CNTF (e.g. Example 11). The claims

encompass increasing neuronal transport of tetanus toxin or TTC in vivo by using BDNF, GDNF or NT-4. The specification fails to provide enabling disclosure for how to increase the transport of tetanus toxin or fusion protein comprising TTC by using BDNF, GDNF, or NT-4 alone without the presence of the tetanus toxin or TTC.

Claims 32 and 33 read on only administering BDNF, GDNF or NT-4 to the neuron but NO tetanus toxin or fusion protein comprising TTC is administered. The specification fails to provide adequate guidance and evidence for how to “increase” neuronal transport of tetanus toxin or TTC without the presence of tetanus toxin or TTC. There is no evidence of record that demonstrates administration of BDNF, GDNF or NT-4 alone to the neuron without the presence of the tetanus toxin or TTC would be able to increase the transport of the tetanus toxin or TTC in a neuron. Absent specific guidance, one skilled in the art at the time of the invention would not know how to “increase” neuronal transport of tetanus toxin or TTC without the presence of tetanus toxin or TTC at the target site.

For the reasons discussed above, it would have required undue experimentation for one skilled in the art at the time of the invention to practice over the full scope of the invention claimed. This is particularly true given the nature of the invention, the state of the prior art, the breadth of the claims, the amount of experimentation necessary, the level of skill which is high, the working examples provided and scarcity of guidance in the specification, and the unpredictable nature of the art.

Conclusion

15. Claims 32 and 33 are rejected. Claims 68-79 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 81-92 are objected. Claims 80 and 93 are in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Shin-Lin Chen, Ph.D.

/Shin-Lin Chen/
Primary Examiner, Art Unit 1632